This Program Announcement expires on November 27, 2002, unless reissued.

INNOVATIONS IN BIOMEDICAL INFORMATION SCIENCE AND TECHNOLOGY: PHASED INNOVATION AWARD (R21/R33)

Release Date: June 29, 2000

PA NUMBER: PA-00-117

Fogarty International Center
National Cancer Institute
National Center for Complementary and Alternative Medicine
National Center for Research Resources
National Eye Institute
National Human Genome Research Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute of Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
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National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Environmental Health Sciences
National Institute of General Medical Sciences
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Library of Medicine

Letter of Intent Receipt Dates: October 27, February 27, and June 27 annually

Application Receipt Dates: November 27, March 27, and July 27 annually
(This solicitation begins with the November 27, 2000, receipt date and ends with the November 27, 2002, receipt date.)

PURPOSE

Participating Institutes and Centers of the National Institutes of Health invite applications for innovative research in biomedical information science and technology to promote the progress of biomedical research.

There exists an expanding opportunity to speed the progress of biomedical research through the power of computing to manage and analyze data and to model biological processes. The NIH is interested in promoting research and developments in biomedical information science and technology that will support rapid progress in areas of scientific opportunity in biomedical research. As defined here, biomedical computing or biomedical information science and technology includes database design, graphical interfaces, querying approaches, data retrieval, data visualization and manipulation, data integration through the development of integrated analytical tools, synthesis, and tools for electronic collaboration, as well as computational research including the development of structural, functional, integrative, and analytical models and simulations.

This program announcement (PA), Innovation in Biomedical Information Science and Technology, will utilize the Phased Innovation Award Mechanism (R21/R33). Specific features of this mechanism will include:

- Single submission and evaluation of both a feasibility/pilot phase (R21) and an expanded development phase (R33) as one application.
- Expedited transition of the R21 feasibility phase to a R33 development phase.
- Flexible budgets.
- Flexible staging of feasibility and development phases.

Small businesses are encouraged to consider a parallel program announcement (TPA-00-110) of identical scientific scope that utilizes the SBIR and STTR mechanisms with accelerated review and transition as well as cost and duration requirements comparable to the Phased Innovation Awards.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010", a PHS-led national activity for setting priority

areas. This Program Announcement (PA), Innovation in Biomedical Information Science and Technology, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/ .

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non- profit, and public and private organizations such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT

This PA will use the National Institutes of Health (NIH) R21 and R33 award mechanisms. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for an application in response to this PA may not exceed 2 years for the R21 phase of a combined application, 3 years for the R33 phase, and 4 years for a combined R21/R33 proposal.

This PA will expire two years from the initial receipt date as indicated by the dates on the front of this solicitation. Awards will be administered under NIH grants policy as stated in the NIH Grants Policy Statement, NIH Publication No 99-8, October 1998.

Support for this program will be through the National Institutes of Health (NIH) Exploratory/Developmental Research Grant (R21) and the Exploratory/Developmental Research Grant Phase 2 (R33). The R33 is a newly established NIH grant mechanism to provide a second phase for the support of innovative exploratory and development research initiated under the R21 mechanism. Transition of the R21 to the R33 phase will be expedited and is dependent on completion of negotiated milestones.

Under this PA, applicants can submit either a combined R21/R33 application (Phased Innovation Award application) or the R33 application alone, if feasibility can be documented, as described in the APPLICATION PROCEDURES section of this program announcement. Applications for R21 support alone will not be accepted.

For combined R21/R33 applications, the R21 phase may not exceed $100,000 direct costs per year. R21 budgets can exceed this cap to accommodate F&A costs to subcontracts to the project. Although the R33 application has no official budgetary limit, applications requesting in excess of $500,000 dollars direct costs in any single year of the grant period require prior approval before submission. It is strongly recommended that applicants contact institute staff at an early stage of application development to convey critical information, such as potentially large budget requests or to discuss programmatic responsiveness of the proposed project. Early contact with institute staff is particularly critical relative to this PA because it uses a new grant mechanism R33 as well as an expedited review procedure. Refer to the INQUIRIES sections of this program announcement for institute staff contacts.

The combined R21/R33 application offers two advantages over the regular application process:

1. Single submission and evaluation of both the R21 and the R33 as one application.

2. Minimal or no funding gap between R21 and R33. The award of R33 funds will be based on program priorities, on the availability of funds and on successful completion of negotiated scientific milestones as determined by institute staff in the context of peer review recommendations.

To be eligible for the Phased Innovation Award, the R21 phase must include well-defined quantifiable milestones that will be used to judge the success of the proposed research, as well as a credible plan for the development of tools or technology for the R33 phase. The Phased Innovation Award must have a section labeled Milestones at the end of the Research Plan of the R21 application. This section must include well-defined quantifiable milestones for completion of the R21 part of the application, a discussion of the suitability of the proposed milestones for assessing the success in the R21 phase, and a discussion of the implications of successful completion of these milestones for the proposed R33 study.

Some NIH institutes and centers may have other grant mechanisms that could apply to biomedical computing projects. Interested participants should contact the institute or center technical contact indicated in the “List of BISTI Contacts” located at the url given in the INQUIRIES section of the announcement.

Through a separate program announcement (PA-00-110), the participating Institutes and Centers of the NIH are inviting applications for SBIR and STTR support, focusing on the identical research areas as described in the RESEARCH OBJECTIVES section of this solicitation. For SBIR/STTR

solicitation, the expedited NIH review and cost allowance policies and procedures will be identical to this PA. Qualified applicants are strongly encouraged to consider responding to the BIR/STTR program announcement. SBIR and STTR application information is available on the Internet at: http://grants.nih.gov/grants/funding/sbir.htm

Potential applicants who believe that they may be eligible for the SBIR/STTR award should consult the PHS SBIR; and STTR Omnibus Solicitation prior to discussions of their eligibility with NIH staff listed under INQUIRIES.

BACKGROUND

Computing and computational tools have become increasingly important in enabling progress in biomedical research. In recognition of the critical role computing will play in biomedical research, the NIH Director commissioned a Working Group on Biomedical Computing to:

Investigate the needs of NIH-supported investigators for computing resources, including hardware, software, networking, algorithms, and training. It should take into account efforts to create a national information infrastructure, and look at working with other agencies (particularly NSF and DOE) to ensure that the research needs of the NIH-funded research community are met.

It should also investigate the impediments biologists face in utilizing high-end computing, such as a paucity of researchers with cross-disciplinary skills. The panel should consider both today's unmet needs and the growing requirements over the next five years (a reasonable horizon for extrapolating the advances in the rapidly changing fields of computing and computational biology).

The result of the deliberations of the Working Group on Biomedical Computing is a report entitled "The Biomedical Information Science and Technology Initiative (BISTI)" which can be accessed at the following site: http://www.nih.gov/welcome/director/060399.htm. A critical recommendation of the BISTI is that the NIH should provide additional resources and incentives for basic research to provide adequate support for those who are inventing, refining, and applying the tools of biomedical computing. The promotion of the interface of biomedical information science and technology with biomedical research should result in new digital and electronic tools that will have substantial impact on broad areas of biomedical research.

The Institutes and Centers of the NIH acknowledge the wisdom of this recommendation and are offering support thorough the current solicitation for fundamental research in biomedical information science and technology as well as for the development of new informatics and computational tools and technologies.

RESEARCH GOALS AND OBJECTIVES

This solicitation targets support for fundamental research in biomedical computing science and technology as well as the development and application of new biocomputing tools or technologies for a particular area(s) of scientific opportunity in biomedical research. Programs may target one or multiple areas of biomedical computing that will enable progress in biomedical research. Examples of data types that could be considered include but are not limited to genomic sequences, biomedical images, qualitative descriptors for health and social science, remote sensing and geospatial images, and chemical formulae. Specific research areas solicited in informatics or computational science include but are not limited to:

- Tools for data collection
- Tools for archiving large data sets
- Research on databases, querying approaches, and information retrieval
- Research on data visualization
- Analysis tools for interpretation of large data sets
- Computing algorithms and new analysis and statistical methodologies for social science research related to areas of biomedical interest such as population aging
- Research on new approaches to data integration
- Development of platform-independent translational tools for data exchange
- Research and development of models or simulation environments
- Tools or models to promote interoperability
- Development of web-based linkage tools for data sharing
- Tools for electronic communication

Areas of biomedical research likely to be critically dependent on biocomputing advances include but are not limited to:

- Behavioral science
- Biological rhythms
- Biomedical imaging
- Cell biology
- Clinical research
- Clinical trials

- Developmental biology
- Drug design at the molecular and cellular levels
- Dynamic modeling of retirement
- Dynamic modeling of health, chronic disease, and disablement
- Endocrinology
- Environmental science
- Epidemiology
- Genetics
- Genomics
- Immunology/inflammation
- Medical genetics
- Morphology
- Neurobiology and cognitive science
- Pharmacology
- Physiology
- Population biology
- Structural biology
- Substance abuse research
- Surgery and virtual tools
- Temporal patterns

Projects must span the interface of biomedical research and biomedical information science and technology. Applications will be expected to demonstrate fundamental understanding and adequate expertise in both the relevant areas of information science and technology and biomedical research. Cross-disciplinary collaborations are strongly encouraged. Applications will also be expected to address the anticipated enabling aspects of the research or development proposed in the context of the targeted area of opportunity in biomedical research the research is expected to benefit.

Given the expanding needs in biomedical research for advances in a variety of areas of information science and technology, the approaches and technologies proposed under this announcement should ultimately be generalizable, scalable, extensible, interoperable and use sophisticated computational resources. The projects should take in to account the needs of the biomedical research community that will be the ultimate end users of the products of the research. The projects should also address plans for ensuring the dissemination of useful products of the research, including approaches, technologies and tools, to the relevant research

and user communities. The informatics and computational research proposed should be future-oriented, fill an area of need or projected need, and seek to exceed the current state-of-the-art.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994, and is also available on the Internet at http://grants.nih.gov/grants/guide/notice-files/not94-100.html .

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the “NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects” that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

Investigators may also obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary for the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

LETTER OF INTENT

Prospective applicants are asked to submit by the dates listed at the beginning of this program announcement a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the PA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows Institute staff to estimate the potential review workload and avoid conflict of interest in the review. The letter of intent is to be sent to the program contact listed under INQUIRIES.

APPLICATION PROCEDURES - SPECIFIC INSTRUCTIONS FOR PREPARING THE COMBINED
R21/R33 PHASED INNOVATION AWARD APPLICATION

Applications for R21/R33 grants are to be submitted on the grant application form PHS 398 (rev. 4/98) and will be accepted at the application deadlines given on the first page of this solicitation. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: grantsinfo@nih.gov.

The R21/R33 application must include the specific aims for each phase and the feasibility milestones that would justify transition to the R33 phase. Applications must include a specific section labeled Milestones following the Research Plan of the R21 phase. Milestones should be well described, quantifiable and scientifically justified. A discussion of the milestones relative to the progress of the R21 phase, as well as, the implications of successful completion of the milestones for the R33 phase should be included. This section should be indicated in the Table of Contents. Applications lacking this information as determined by the NIH program staff, will be

returned to the applicant without review. For funded applications, completion of the R21 milestones will elicit an NIH expedited review that will determine whether or not the R33 should be awarded. The release of R33 funds will be based on successful completion of negotiated scientific milestones, program priorities, and on the availability of funds. The expedited review may result in additional negotiations of award.

The R21/R33 Phased Innovation Award application must be submitted as a single application, with one face page. Although it is submitted as a single application, it should be clearly organized into two phases. To accomplish a clear distinction between the two phases, applicants are directed to complete Sections a-d of the Research Plan twice: one write-up of Sections a-d and milestones for the R21 phase and sections a-d again for the R33 phase. The Form 398 Table of Contents should be modified to show sections a-d for each phase as well as the milestones. There is a page limit of 25 pages for the composite a-d text (i.e., section a-d and milestones for the R21 and sections a-d for the R33 phase must be contained within the 25 page limit.)

In preparing the R21/R33 application, investigators should consider the fact that applications will be assigned a single priority score. Thus,clarity and completeness of the R21/R33 application with regard to specific goals and feasibility milestones for each phase are critical. The presentation of milestones that are not sufficiently scientifically rigorous to be valid for assessing progress in the R21 phase will reflect upon the scientific judgement of the applicant in this proposal.

1. Face Page of the application:

Item 2. Check the box marked "YES" and type the number and title of this program announcement. Also indicate if the application is a R21/33 or R33.

Item 7a: DIRECT COSTS REQUESTED FOR INITIAL PERIOD OF SUPPORT

For the R21 phase of the combined R21/R33 application, direct costs are limited to a maximum of $100,000 per year for a maximum of two years and the award may not be used to supplement an ongoing project. The requested budgets can exceed this cap to accommodate for F&A costs to subcontracts to the project. Insert the first year of R21 support in item 7a Item 8a, DIRECT COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT:

For the R21 phase, direct costs requested for the proposed period may not exceed $200,000 for two years of support. The statement in item 7a above pertaining to subcontract costs also applies here. Insert sum of all years of requested support in item 8a

2. Page 2 - Description:

As part of the description, identify concisely the fundamental research and/or technology or tool to be developed, its innovative nature, its relationship to presently available capabilities, and its expected impact on biomedical information science and technology and biomedical research.

3. Budget: The application should provide a detailed budget for Initial Budget Period (form page 4), for each of the initial years of the R21 and R33 phases as well as a budget for the entire proposed period of support (form page 5). Form pages should indicate which years are R21 and R33. All budgets should include a written justification.

An annual meeting of all investigators funded through this program will be held to share progress and research insights that may further progress in the program. Applicants should request travel funds in their budgets for the principal investigator and one additional senior investigator to attend this annual meeting.

4. Research Plan:

Item a: Specific Aims.

The applicants must present specific aims that the applicant considers to be scientifically appropriate for the relevant phases of the project.

The instructions in the PHS 398 booklet for this section of research grant applications suggest that the applicant state the hypotheses to be tested. Since the goal of this PA is to develop fundamental understanding, innovative technologies, and tools, hypothesis testing per se may not be the driving force in developing such a proposal and, therefore, may not be applicable. Furthermore for R21 grant applications, preliminary data are not required, although they should be included when available. For both the R21 and R33 phase, research that develops new fundamental understanding, technologies, or tools is likely to require the application of principles of fields such as computer science, mathematics, and engineering. Clear statements of these underlying principles within this section are essential.

Item b: Background and Significance

Elaborate on the innovative nature of the proposed research. Clarify how the fundamental research or tools or technologies to be developed as proposed in this project will result in a significant improvement over existing approaches. Explain the potential of the proposed technology for having a broad impact on a compelling area of biomedical research. Clearly identify how the project, if successful, would result in new capabilities for research, the immediacy of the opportunity and how any proposed technologies or tools would differ from existing technologies or tools.

Item c: Preliminary Studies/Progress Report

While preliminary data are not required for submission of the R21 phase, this section should provide current thinking or evidence in the field to substantiate feasibility of the R21 phase. The R33 need not repeat information already provided in the R21. In the event that an applicant feels that some aspect of the approach or tools or technology to be developed is too proprietary to disclose, applicants at a minimum should provide a demonstration (results) of the capabilities of the proposed approach, tool or technology.

Item d: Research Design and Methods

Follow the instructions in the PHS 398 booklet. For this particular program, applicants should also address plans to make the products, tools, or technologies forthcoming from this research available to the relevant biomedical research user community. In addition, for the R21 phase only, the following information must be included as a final section of Item d:

Applications must include a specific section labeled Milestones following the Research Design and Methods of the R21 phase. Milestones should be well described, quantifiable, and scientifically justified and not be simply a restatement of the specific aims. A discussion of the milestones relative to the success of the R21 phase, as well as the implications of successful completion of the milestones for the R33 phase and the page number of the milestones section should be listed. This section should be indicated in the Table of Contents.

Applications lacking this information as determined by the Institute program staff, will be returned to the applicant without review. For funded applications, completion of the R21 milestones will elicit an Institute expedited review that will determine whether or not the R33 should be awarded. The release of R33 funds will be based on successful completion of milestones, program

priorities and on the availability of funds. The expedited review may result in additional negotiations of award.

SPECIFIC INSTRUCTIONS FOR PREPARATION OF THE R33 APPLICATION WHEN SUBMITTED WITHOUT THE R21 PHASE.

Applications for R33 grants are to be submitted on the grant application form PHS 398 (rev. 4/98) and prepared according to the instructions provided unless specified otherwise within items 1-5 below. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email:grantsinfo@nih.gov.

1. Face Page of the application:

Item 2. Check the box marked "YES" and type the number and title of this program announcement and indicate R33.

2. Page 2 - Description:

As part of the description, identify concisely the fundamental research and/or technology or tool to be developed, its innovative nature, its relationship to presently available capabilities, and its expected impact on biomedical information science and technology and biomedical research.

3. Research Plan:

Item a: Specific Aims.

The instructions in the PHS 398 booklet for this section of research grant applications suggest that the applicant state the hypotheses to be tested. Since the goal of this PA is to develop fundamental understanding, innovative technologies, and tools, hypothesis testing per se may not be the driving force in developing such a proposal and, therefore, may not be applicable. Research that develops new fundamental understanding, technologies, or tools is likely to require the application of principles of fields such as computer science, mathematics, and engineering. Clear statements of these underlying principles within this section are essential.

Item b: Background and Significance

Elaborate on the innovative nature of the proposed research. Clarify how the fundamental research or tools or technologies to be developed as proposed in this project will result in a significant improvement over existing approaches. Explain the potential of the proposed technology for having a broad impact on a compelling area of biomedical research. Clearly identify how the project, if successful, would result in new capabilities for research, the immediacy of the opportunity and how any proposed technologies or tools would differ from existing technologies or tools.

Item c: Preliminary Studies/Progress Report

This section must document that feasibility studies have been completed, and progress achieved, equivalent to that expected through the support of an R21 project. The application must clearly describe how the exploratory/developmental study is ready to scale up to an expanded development stage. In the event that an applicant feels that some aspect of the approach or tools or technology to be developed is too proprietary to disclose, applicants at a minimum should provide a demonstration (results) of the capabilities of the proposed approach, tool or technology.

Item d: Research Design and Methods

Follow the instructions in the PHS 398 booklet. For this particular program, applicants should also address plans to make the products, tools or technologies forthcoming from this research available to the relevant biomedical research user community.

FOR ALL APPLICATIONS

Appendix: All instructions in the Form 398 application kit apply.

Submit the completed and signed original of the application and five legible and signed copies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

Applications must be received by the application deadline dates given on the first page of this solicitation. If an application is received after that date, it will be returned to the applicant without review. The Center for Scientific Review (CSR) will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be evaluated for scientific and technical merit by an appropriate scientific review group convened in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit (generally the top half of applications under review) will be discussed, assigned a priority score, and receive a second-level review by the appropriate national advisory council or board.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. The reviewers will comment on the following aspects of the application in their written critiques in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered by the reviewers in assigning the overall score weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a technology forward.

1. Significance.
- o Does this study address an important problem?
- o Are the results of the study likely to enable a compelling area of biomedical research?
- o If the aims of the application are achieved, how will scientific knowledge be advanced?
- o What will be the effect of these studies on the concepts or methods that drive this field?

o To what degree does the research or development of technologies or tools support the needs of the targeted biomedical research community?
o For systems intended for clinical research or use the additional criteria will be considered:
? to what degree is the approach, technology or tool appropriate for clinical research and likely to have utility in a clinical setting?
? do applicants adequately address such issues as the protection of patient information and confidentiality?

2. Approach.
o Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?
o Does the applicant acknowledge potential problem areas and consider alternative tactics?
o What is the time frame for developing the proposed approaches, tools, or technologies and suitability of this time frame for meeting the needs of the relevant biomedical research community's needs?
o How easy will it be to use the proposed approach, tool, or technology?
o Are the plans for dissemination of the proposed endpoints, tools or technologies of the project adequate?

3. Milestones.
o How appropriate are the proposed milestones against which to evaluate the demonstration of feasibility for transition to the R33 development phase?

4. Innovation.
o Does the project employ novel concepts, approaches or method?
o Are the aims original and innovative?
o Does the project challenge existing paradigms or develop new methodologies or technologies?
o Does the project adequately address end user needs?
o Will there be additional application opportunities for the approach, technology or tool proposed?
o Does the project use high-end computing?

5. Investigator.
o Is the investigator appropriately trained and well suited to carry out this work?
o Does the project team have adequate expertise in both the areas of biomedical information science and technology and biomedical research?

o Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

6. Environment.
o Does the scientific environment in which the work will be done contribute to the probability of success?
o Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?
o Is there evidence of institutional support?

Additional Considerations

For the R21/R33 Phased Innovation Award Application, the initial review group will evaluate the specific goals for each phase and the feasibility milestones that would justify expansion to the R33 phase. A single priority score will be assigned to each scored application. As with any grant application, the initial review group has the option of recommending support for a shorter duration than that requested by the applicant, and basing the final merit rating on the recommended portion of the application.

The initial review group will also examine the appropriateness of the proposed project budget and duration; the adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research and plans for the recruitment and retention of subjects; the provisions for the protection of human and animal subjects; and the safety of the research environment as well as plans for including children as appropriate for the scientific goals of the research, or justification for exclusion. (See section on NIH POLICY AND GUIDELINES ON THE INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS).

AWARD CRITERIA

Applications will compete for available funds with all other recommended applications. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review, availability of funds, and program priority.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries or contacts concerning institute-specific technical or financial issues should be directed to the NIH BISTI technical or financial contacts listed at the following Web site: http://grants.nih.gov/grants/bistic/bistic_contacts.cfm .

Inquiries regarding general programmatic issues and notices of intent should be directed to:

Dr. James Cassatt
NIGMS
45 Center Drive
Bethesda, MD 20892-6200
TEL: 301-594-0828
FAX: 301-480-2004
Email: jc12b@nih.gov

Inquiries regarding review issues should be directed to:

Elliot Postow, Ph.D.
Center for Scientific Review
6701 Rockledge Drive
Bethesda, MD 20892
TEL: (301) 435-0911
FAX: (301) 480-2241
Email: postowe@csr.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.394, Cancer Detection and Diagnosis Research. Awards are made under authorization of the Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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